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ADDITIONAL INFORMATION ON SMALL ENTITY IMPACTS OF THE AMENDED PROPOSED TSCA SECTION 4(a) TEST RULE FOR 21 HAZARDOUS AIR POLLUTANTS

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1.0 INTRODUCTION

This document provides more information about EPA's analysis of small entity impacts under the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Act (SBREFA), for the proposed test rule for 21 hazardous air pollutants (HAPs) published on June 26, 1996.[1] In that analysis, EPA stated that the proposed rule would not have a significant impact on small businesses (entities) because health effects testing of chemicals is generally carried out by consortia of the large manufacturers or importers of the chemicals. Based on such testing arrangements, it was considered unlikely that reimbursement by small entities would be required. This analysis examines the potential impact on small entities that would occur if they were to share the costs of required health effects testing. The Agency's overall conclusions on small entities has not changed.

This report does not contain TSCA Confidential Business Information (CBI), although TSCA CBI information sources were used in its preparation. Publicly available data on producers, production volumes, and other market information for the 21 HAP chemicals can be found in the accompanying economic analysis for this rule.[2]

2.0 DESCRIPTION OF THE RULE

The test rule for 21 hazardous air pollutants (HAPs) was proposed under the authority of section 4(a) of the Toxic Substances Control Act (TSCA). EPA is issuing an amended HAPs proposal with 11 new TSCA test guidelines (799 series)[3] that replace the guidelines used in the original proposal. EPA is incorporating the estimated costs associated with testing conducted under the new guidelines into this analysis.

Under TSCA section 4(a), EPA is authorized to require by rule that manufacturers and processors of chemical substances conduct testing to determine the effect of chemical substances on human health and the environment. Test rules may be promulgated for any chemical substance that (a) may present an unreasonable risk of injury to health or the environment; or (b) is or will be produced in substantial quantities and may either enter the environment in substantial quantities or result in substantial human exposure to the chemical. Once a finding under (a) or (b) above is made, EPA may then require health effects or environmental testing that is deemed necessary to address unanswered questions about the effects of the chemical substance that pertain to the issue of unreasonable risk of injury to health or the environment.

As detailed below in Section 3.1.2, this rule would apply to manufacturers (including importers) of each subject HAP chemical. The amended proposal also includes notification requirements under TSCA section 12(b) applicable to exporters as explained in Section 2.2.

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[1] 61 FR 33178, 33196.

[2] *Economic Assessment for Amended Proposed TSCA Section 4(a) Rule for 21 Hazardous Air Pollutants*, Non-CBI Version, prepared by EPA/OPPT/EETD/EPAB with the support of Abt Associates Inc. and Eastern Research Group, Inc., November 14, 1997.

[3] 62 FR 43820, (August 15, 1997).

2.1 Identification of Chemicals

For this test rule, EPA is using its TSCA section 4(a) authority to obtain data necessary to implement section 112 of the Clean Air Act, which provides for the assessment and management of hazardous air pollutants. The specific HAP chemicals addressed by this rule are shown in Table 1 along with their Chemical Abstracts Service (CAS) numbers.

Table 1. Hazardous Air Pollutants Covered by the Amended HAPs Proposal

No.	CAS No.	Chemical
1	75-35-4	Vinylidene Chloride
2	79-00-5	1,1,2-Trichloroethane
3	80-62-6	Methyl Methacrylate
4	85-44-9	Phthalic Anhydride
5	91-20-3	Naphthalene
6	92-52-4	1,1' - Biphenyl
7	100-41-4	Ethylbenzene
8	107-06-2	Ethylene Dichloride
9	107-21-1	Ethylene Glycol
10	108-10-1	Methyl Isobutyl Ketone
11	108-31-6	Maleic Anhydride
12	108-90-7	Chlorobenzene
13	108-95-2	Phenol
14	111-42-2	Diethanolamine
15	120-82-1	1,2,4-Trichlorobenzene
16	126-99-8	Chloroprene
17	463-58-1	Carbonyl Sulfide
18	 95-48-7 106-44-5 108-39-4	Cresols (ortho-isomer) (para-isomer) (meta-isomer)
19	7647-01-0	Hydrochloric Acid
20	7664-39-3	Hydrogen Fluoride
21	7782-50-5	Chlorine

Of these chemicals, 20 are commercially produced and one (carbonyl sulfide, CAS No. 463-58-1) is a byproduct and is not commercially produced.

2.2 Relationship of the Rule to Export Notification Requirements

According to regulations promulgated under TSCA section 12(b), all exporters of chemicals for which the submission of data is required under TSCA section 4(a) must give EPA a one-time notification for each country to which a subject chemical is shipped. In addition to analyzing the potential impacts of the rule on small manufacturers and importers, this report also considers the potential impact on small exporters.

3.0 SMALL ENTITY ANALYSIS REQUIREMENTS

This small entity analysis was prepared to supplement EPA's analysis of the potential impact of the amended HAPs test rule on small entities. Since its passage in 1980, the RFA has required every federal agency to prepare a regulatory flexibility analysis for any notice-and-comment rule it issues, *unless* the agency certifies that the rule

> "will not, if promulgated, have a significant economic impact on a substantial number of small entities."

The legal test for certifying a rule has two steps: first, will the impact on any small entities subject to the rule be significant, and second, will the number of small entities significantly impacted be substantial? The Agency may certify a rule if its impact is significant but only with respect to a small number or percentage (i.e. not a "substantial number") of the small entities subject to the rule's requirements. The Agency may also certify a rule if its impact falls on a substantial number of small entities, but its impact is not significant.[4] If a rule is determined not to have a significant economic impact on a substantial number of small entities, no further analysis is required under the RFA.

Three factors are examined in order to characterize the small entity impacts of a rule: 1) the size of the adverse impact (measured as the ratio of the cost to sales or revenues), 2) the total number of small entities that experience the adverse impact, and 3) the percentage of the total number of small entities that experience the adverse impact. In general, EPA believes that a rule can be considered as not having a significant economic impact on a substantial number of small entities if it satisfies one of the conditions shown in Table 2.

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[4] *EPA Interim Guidance for Implementing the Small Business Regulatory Enforcement Fairness Act and Related Provisions of the Regulatory Flexibility Act*, February 5, 1997, prepared by the EPA SBREFA Task Force, pp. 1-14.

Table 2. General Criteria for Qualifying Regulatory Impacts
(No Significant Impact on a Substantial Number of Small Entities)

Size of Economic Impact	Number of Small Entities Experiencing this Economic Impact	Prior column as Percent of All Affected Small Entities
Cost/Sales is less than 1% for all affected small entities	Any number	Any percent
Cost/Sales is 1% or greater for one or more small entities	Fewer than 100	Any percent
Cost/Sales is 1% or greater for one or more small entities	100 to 999	Less than 20%
Cost/Sales is 3% or greater for one or more small entities	Fewer than 100	Any percent

This report considers two classes of affected entities: (1) small manufacturers (including importers) and processors who would be subject to the testing requirements of the rule; and (2) small exporters, who would become subject to TSCA section 12(b) notification requirements. The treatment of processors is explained in section 3.1.2 below.

3.1 Overview of Analytical Procedure

This analysis provides further information about the potential for the amended proposed TSCA section 4(a) rulemaking for Hazardous Air Pollutants (HAPs) to have a significant impact on a substantial number of small entities. The major steps in the analysis are as follows:

- Identify manufacturers and importers of each HAP chemical
- Determine whether each manufacturer or importer is "initially burdened"
- Determine the number of initially burdened companies that are small entities for RFA purposes
- Calculate each small manufacturer or importer's share of testing costs for each chemical
- Determine the significance of the test cost burden
- Determine impacts on exporters

These steps are described in the sections below.

3.1.1 Number of Manufacturers and Importers Affected

To identify producers and importers of the 21 HAPs chemicals, EPA performed a search of the most recent EPA TSCA Chemical Inventory Chemical Update System (CUS) records. Manufacturers or importers of chemicals listed in the TSCA Chemical Inventory are required to provide quadrennial reports to EPA on

their production or import volumes. EPA considers the CUS records to be the best available source of facility-level production and import data for most of the HAP chemicals because the data are required to be submitted by statute and are submitted to EPA as confidential business information.[5]

As indicated above, one of the chemicals (carbonyl sulfide, CAS No. 463-58-1) is a byproduct and is not commercially produced. Since the TSCA Chemical Inventory only covers chemicals in commerce, it was necessary to use alternate data sources to identify companies that produce this chemical as a byproduct.[6] For three other HAP chemicals (all inorganic chemicals), the TSCA Chemical Inventory did not contain sufficient data, and industry data sources were used instead.[7]

Based on the data collected from these sources, a total of 386 manufacturers/importers were identified (283 manufacturers and 103 importers).[8,9]

3.1.2 Identification of Initially Burdened Entities

Under 40 CFR 790.42, each test rule must indicate whether manufacturers (including importers), processors, or both are subject to testing requirements. This determination will depend on whether testing is required to evaluate the risks associated primarily with manufacture of the chemical, processing of the chemical, or both. The proposed HAPs test rule indicates that manufacturers (including importers) and processors would be subject to the rule.

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[5] As the size cutoff for reporting to the TSCA Chemical Inventory is 10,000 pounds per year, it is possible that some producers of one or more of the subject HAP chemicals may not be captured by this analysis.

[6] The details of this data collection are described in Appendix A.

[7] EPA used "Chemical Product Synopses" from Mannsville Chemical Products Corp. to identify U.S. producers of chlorine (CAS No. 7782-50-5) and hydrogen fluoride (CAS No. 7664-39-3). For hydrochloric acid (CAS No. 7647-01-0), EPA used data from "Hydrochloric Acid (Chemical Profile)," Chemical Marketing Reporter, September 25, 1995.

[8] 386 represents the sum of the number of manufacturers/importers on a HAP chemical by HAP chemical basis. To the extent that some facilities manufacturer/import more than one HAP chemical, the total number of manufacturers/importers affected by the rule may be lower. Since the impacts of the rule are being evaluated on a HAP chemical by HAP chemical basis, however, all of the components of the impact analysis are presented on a HAP chemical by HAP chemical basis. Companies that produce the byproduct carbonyl sulfide are classified as manufacturers in these counts.

[9] For the chemicals noted in footnote 7, the data sources identified only manufacturers. An unknown number of importers of these chemicals may also be affected by the proposed rule, but cannot be identified through these or other data sources. In addition, the data source for hydrochloric acid covers only manufacturers with combined production capacity at all facilities of 50,000 tons (100 million pounds) per year, and that an estimated 23 smaller producers with combined capacity of 460,000 tons (920 million pounds) are excluded from the data.

According to 40 CFR 790.42(a)(2), while legally subject to the HAPs test rule, processors of a HAP chemical would be required to comply with the requirements of the rule only if they are directed to do so in a subsequent notice as set forth in 40 CFR 790.48(b). EPA would only issue such a notice if no manufacturer or importer submits a notice of its intent to conduct testing. The Agency has never notified processors of their obligation to test under such a notice, or applied the reimbursement procedures of 40 CFR 791 to processors or even to manufacturers. Since EPA has identified at least one manufacturer or importer for each HAP chemical, the Agency presumes that at least one such manufacturer or importer would submit a notice of intent to conduct testing for each chemical and would actually conduct such testing, and thus that processors would not, at least initially, be burdened with the need to comply with the rule.

In addition, according to 40 CFR 790.42(a)(4), entities that manufacture/import less than 500 kg (1,100 lb) of the chemical annually would also not considered to be initially burdened since they would be required to comply with the requirements of the test rule only if they are directed to do so in a subsequent notice as set forth in 40 CFR 790.48(b). Similarly, under 40 CFR 790.42(a)(5), entities that manufacture or import small quantities of the chemical solely for research and development (R&D) purposes would be considered not to be initially burdened.

Thus, in the analysis that follows, processors of the subject chemicals are not included, nor are manufacturers/importers of less than 500 kg of a subject chemical, nor are entities that manufacture or import only small quantities for R&D purposes.

The analysis covers entities that manufacture/import 500 kg (1,100 lb) or more of any of the subject chemicals.[10] These entities are defined in this analysis as "initially burdened" in the sense that, under 40 CFR 790.45, following promulgation of the test rule, they would be required to submit a notification of intent to conduct testing or an application for an exemption from testing requirements. This analysis only accounts for the costs of complying with testing requirements since such costs are expected to exceed the costs of applying for testing exemptions. As this analysis does not account for the 25,000 lb. volume threshold or the one percent *de minimis* provision in the amended HAPs proposal, this analysis may include more small entities than would be actually affected by the HAPs test rule.

This analysis assumes that manufacturers of HAP chemicals as byproducts or impurities have the same industry profile as product manufacturers. Test cost sharing by byproduct and impurity manufacturers would spread the cost of testing more broadly, impacting each affected entity to a lesser degree.

3.1.3 Number of Manufacturers/Importers Initially Burdened

Beginning with the initial list of manufacturers/importers, an initial screen was used to eliminate manufacturers or importers who will not be initially burdened. Of the 386 manufacturers/importers identified, 21 were determined to be not initially burdened due to their manufacture/import volumes (i.e.,

[10] Production of carbonyl sulfide (CAS No. 463-58-1) as a byproduct is considered manufacturing under the proposed rule.

they manufactured or imported less than 500 kg). The total number of manufacturers/importers initially burdened, therefore, is 365.[11]

3.1.4 Definition of Small Manufacturer/Importer

A second screen was used to identify manufacturers or importers who qualify as small under the definition of small manufacturer/importer specified at 40 CFR 704.3. Under this definition, a manufacturer or importer is small if it meets either of the following criteria: (1) total annual sales of the company, combined with those of any parent company, are below $40 million *and* annual production volume or importation volume at the facility is less than or equal to 100,000 pounds; or (2) total annual sales of the company, combined with those of any parent company, are below $4 million. The definition also includes a provision that allows the Agency to adjust the total annual sales values for inflation whenever the Agency deems it necessary to do so.

3.1.5 Total Number of Small Manufacturers/Importers Burdened

Since the sales of any ultimate parent company are relevant in determining size, the revenues of the ultimate parent company were used to determine whether a manufacturer or importer is "small" for purposes of assessing the impacts of the proposed rule. For each manufacturer/importer, therefore, EPA attempted to identify the parent company, or "ultimate corporate entity," and obtain data on annual revenues for this entity. The ultimate corporate entity (UCE) is the top-most firm of a family of companies.

The UCEs were identified through a search of Dun and Bradstreet (D&B) facility files for each initially burdened manufacturer or importer.[12] Among other information, the D&B records indicate whether the manufacturer or importer itself is a UCE (i.e., a headquarters or single location). If not, the record includes the D&B number for the UCE. The D&B number for the UCE can then be used to locate the D&B record for the top-most firm of a family of companies. Depending on whether the manufacturer/importer was itself a UCE, either its revenues or those of the UCE were extracted for use in this analysis.

In some cases, the UCE for a manufacturer/importer could not be identified, either because no D&B record was available for the UCE, or because the record did not contain revenue data for this entity. However, in some cases, the subsidiary manufacturer/importer itself had revenues that, alone or combined with the production volume criteria, classified it as not small. In other cases, it was possible to identify a sister company that exceeded the sales size criteria. Where this occurred, there was sufficient information to classify the facility as "not small" under the definition of small manufacturer/importer because, as noted above, the definition combines revenues of the manufacturer/importer with those of the UCE to determine size. (If the facility itself or a sister company is not small, the UCE is also not small). In these cases, the

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[11] 365 represents the sum of the number of initially burdened manufacturers/importers on a HAP chemical by HAP chemical basis. To the extent that some facilities manufacturer/import more than one HAP chemical, the total number of manufacturers/importers affected by the rule is expected to be lower.

[12] *Dun's Marketing Information Services*, April 1997 version, accessed through EPA's "Finds" system located on the Agency's mainframe computer.

revenue data for the subsidiary or sister entity were used in lieu of data for the UCE. Based on this, there are a total of 14 confirmed UCEs that are small, according to the TSCA definition.

For a small number of manufacturers/importers there were no revenue data available for the UCE, *and* it was not possible to conclude, based on the available revenue data for the manufacturer/importer itself, that the affected entity was not small. In these cases, the manufacturer/importer was included as a possible small entity (i.e., a worst-case assumption was made). From a total of 365 initially burdened manufacturers/importers, revenue data for the UCE were unavailable for 8 facilities.[13]

According to this analysis, there are a total of 239 UCEs associated with the 365 initially burdened manufacturers/importers on a HAP chemical by HAP chemical basis. Of the 239 UCEs, 14 were confirmed to be small according to the TSCA definition, while there are another 8 for which revenue data were not available and which are assumed to be small as a worst-case assumption. Thus, there are a maximum of 22 small UCEs affected by the proposed rule.

3.1.6 Manufacturers' and Importers' Testing Costs

For the analysis shown in this report, the "best" cost estimate of testing requirements for each chemical was used. These costs are based on the costs reported in the 1995 Economic Analysis for the proposed HAPs test rule, and modified by additional cost estimates for test guidelines developed by EPA since that report was completed (see Appendix B).

Total testing costs of the amended TSCA section 4(a) proposal range from $87,536 to $3.0 million per chemical, including associated administrative costs incurred by companies subject to the rule. The administrative costs are estimated to be 25 percent of the laboratory costs. The best estimate of the total costs of testing for all chemicals is $30.3 million.[14] Consistent with the Economic Analysis, the total test costs have been annualized over a 15-year period using a 7 percent discount rate. The annualized test costs, as shown in Table 3, range from $9,611 to $325,401 per chemical. The best estimate of the total annualized test costs for all HAPs chemicals is $3.3 million per year.

EPA understands that methods for distributing the costs of chemical-specific testing have generally been worked out independently by industry groups based on production/import volume share. For purposes of this analysis, EPA assumes that the costs of performing chemical-specific testing will be borne by manufacturers/importers in proportion to their production/import volume. To calculate the cost shares, production/import volumes for each chemical were first aggregated to the level of the UCE, since the economic impact test is based on the revenues of the UCE. Thus, if Company X (a UCE) operates three plants that manufacture Chemical Y, Company X's share of test costs for Chemical Y is calculated based on the *combined* production volume of the three facilities.

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[13] These 8 facilities correspond to 6 UCEs, as 1 UCE operates 3 facilities making 3 separate HAP chemicals. Therefore, Table 4 shows 8 UCEs on a HAP chemical by HAP chemical basis.

[14] See Appendix B and Unit IV of the economic assessment for additional information on the costs of testing under the amended HAPs proposal.

Costs for testing the 3 cresol isomers (CAS Nos. 95-48-7, 106-44-5, and 108-39-4) were determined separately for each isomer and applied separately to manufacturers/importers of each of the 3 isomers. Producers of mixed cresol isomers (CAS No. 1319-77-3) that produce mixtures containing one or more of these isomers would also be subject to the HAPs rule.[15]

Although carbonyl sulfide is a byproduct, the same basic analysis is applied. Thus, if Company X (a UCE) operates three facilities that by-produce carbonyl sulfide, Company X's share of test costs for carbonyl sulfide is calculated based on the *combined* byproduction volume of the three facilities.

Table 3. Testing Costs for HAP Chemicals*

No.	CAS No.	Chemical Name	Annualized Testing Costs ($1997)		
			Best	Minimum	Maximum
1	75-35-4	Vinylidene Chloride	$46,801	$37,835	$56,530
2	79-00-5	1,1,2-Trichloroethane	$322,386	$244,141	$421,570
3	80-62-6	Methyl Methacrylate	$165,299	$127,879	$212,413
4	85-44-9	Phthalic Anhydride	$315,219	$238,293	$412,984
5	91-20-3	Naphthalene	$97,359	$73,539	$129,854
6	92-52-4	1,1'-Biphenyl	$210,375	$154,434	$276,483
7	100-41-4	Ethylbenzene	$165,299	$127,879	$212,413
8	107-06-2	Ethylene Dichloride	$200,337	$147,188	$263,251
9	107-21-1	Ethylene Glycol	$101,914	$71,637	$133,832
10	108-10-1	Methyl Isobutyl Ketone	$97,359	$73,539	$129,854
11	108-31-6	Maleic Anhydride	$192,433	$153,260	$243,840
12	108-90-7	Chlorobenzene	$101,914	$71,637	$133,832
13	108-95-2	Phenol	$19,649	$15,061	$24,781
14	111-42-2	Diethanolamine	$210,375	$154,434	$276,483
15	120-82-1	1,2,4-Trichlorobenzene	$87,589	$69,401	$107,339
16	126-99-8	Chloroprene	$134,548	$103,560	$174,836
17	463-58-1	Carbonyl Sulfide	$325,401	$246,499	$425,289
18		Cresols			
	95-48-7	(ortho-isomer)	$101,914	$71,637	$133,832
	106-44-5	(para-isomer)	$101,914	$71,637	$133,832
	108-39-4	(meta-isomer)	$101,914	$71,637	$133,832
19	7647-01-0	Hydrochloric Acid	$9,611	$7,815	$11,549
20	7664-39-3	Hydrogen Fluoride	$210,375	$154,434	$276,483
21	7782-50-5	Chlorine	$9,611	$7,815	$11,549
TOTAL			$3,329,594	$2,495,192	$4,336,660

* Includes laboratory costs (see Appendix B) and associated administrative costs incurred by companies subject to the rule.

[15] According to CUS and D&B records there are no small manufacturers/importers of mixed cresol isomers.

3.1.7 Significance of the Test Cost Burden

EPA next compared each small UCE's share of testing costs, on a HAP chemical by HAP chemical basis, to its revenues. For this report, the revenue measure used is the total revenues for the UCE as reported in Dun's Marketing Information Service.[16]

As explained in Table 2, this analysis uses a series of criteria to assess the rule's potential impact on small entities. These criteria are based on a combination of size of impact and number of small entities impacted. The first criterion is whether the cost impact is less than 1 percent for all affected small entities. Of the 14 confirmed small UCEs subject to the proposed rule, none would be impacted at greater than 1 percent based on the annualized test costs in Table 3. Only the 6 entities (associated with 8 HAPs chemicals) of indeterminate size may be impacted at greater than 1 percent as a worst-case assumption.

Under the second criterion, a rule would be unlikely to have a significant economic impact on a substantial number of small entities if the impacts are 1 percent or greater for fewer than 100 affected small entities. As shown above (see section 3.1.5 "Total Number of Small Manufacturers/Importers Burdened"), the maximum number of small entities initially burdened by the rule is 22, and the maximum number affected at 1 percent or greater is 6 (or 8, on a HAP chemical by HAP chemical basis). Based on this criterion, the amended HAPs test rule proposal would not have a significant economic impact on a substantial number of small entities. No other information available for this report indicates any other reason to believe that there would be a significant economic impact on a substantial number of small entities

3.1.8 Summary of Impacts Analysis for Manufacturers/Importers

Table 4 summarizes all of the above analysis for manufacturers and importers. For each chemical, columns numbered 1, 2 and 3 indicate as follows: the number of individual manufacturers/importers (column 1), the number of individual manufacturers/importers initially burdened (column 2), and the number of UCEs initially burdened on a HAP chemical by HAP chemical basis (column 3). The UCEs in Column 3 would share the testing costs.

Column 4 indicates that there are a total of 14 UCEs which would share the test costs and which are *small*, as defined at 40 CFR 704.3. Column 5 indicates there are 8 UCEs whose size cannot be determined and which are therefore considered small throughout the rest of the analysis, as a worst-case assumption. Column 6 adds Columns 4 and 5 together as the worst-case estimate of the number of small entities affected by the HAPs rule. The worst-case estimate of the total number of small entities is 22.

In Column 7, the impact test is applied. Here, UCEs that are both small *and* impacted by costs equal to or exceeding 1 percent of revenues are identified. As shown, there are no small entities impacted at the 1 percent or greater level. Column 8 concludes that the worst-case estimate of the number of small entities potentially impacted at 1 percent or greater is therefore 8.

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[16] April 1997 version, accessed through EPA's "Finds" system located on the Agency's mainframe computer.

Table 4. Summary of Results from Small Entity Impact Analysis

Chemical	1. No. of Manufacturers/ Importers	2. No. of Initially Burdened Manufacturers/ Importers	3. No. of Initially Burdened UCEs	4. Of UCEs Sharing Test Costs, Number of Small Entities	5. Of UCEs Sharing Test Costs, Number of Unknown Size	6. Worst-Case Estimate of Small Entities	7. No. of Confirmed Small Entities Impacted at >1%	8. Worst-Case Estimate of Small Entities Impacted at >1%
75-35-4 Vinylidene Chloride	2	2	2	0	0	0	0	0
79-00-5 1,1,2-Trichloroethane	4	4	4	0	0	0	0	0
80-62-6 Methyl Methacrylate	14	14	10	1	0	1	0	0
85-44-9 Phthalic Anhydride	18	18	15	2	0	2	0	0
91-20-3 Naphthalene	9	9	9	0	1	1	0	1
92-52-4 1,1'-Biphenyl	7	7	5	0	0	0	0	0
100-41-4 Ethylbenzene	34	34	24	1	0	1	0	0
107-06-2 Ethylene Dichloride	25	25	15	0	0	0	0	0
107-21-1 Ethylene Glycol	43	43	31	1	2	3	0	2
108-10-1 Methyl Isobutyl Ketone	13	13	12	3	0	3	0	0
108-31-6 Maleic Anhydride	12	12	12	4	1	5	0	1
108-90-7 Chlorobenzene	6	6	5	0	0	0	0	0
108-95-2 Phenol	15	14	12	1	1	2	0	1
111-42-2 Diethanolamine	6	6	5	1	0	1	0	0
120-82-1 1,2,4-Trichlorobenzene	3	3	3	0	0	0	0	0
126-99-8 Chloroprene	2	2	2	0	0	0	0	0
463-58-1 Carbonyl Sulfide	68	48	23	0	0	0	0	0
Cresols								
95-48-7 o-isomer	4	4	3	0	1	1	0	1
106-44-5 p-isomer	6	6	4	0	2	2	0	2
108-39-4 m-isomer	5	5	3	0	0	0	0	0
7647-01-0 Hydrochloric Acid	50	50	20	0	0	0	0	0
7664-39-3 Hydrogen Fluoride	2	3	3	0	0	0	0	0
7782-50-5 Chlorine	37	37	17	0	0	0	0	0
TOTALS	386	365	239	14	8	22	0	8

3.2 Impacts on Exporters

When finalized, the amended HAPs test rule proposal would subject the 21 HAP chemicals to testing under TSCA section 4(a). Under TSCA section 12(b), all exporters of chemicals for which the submission of data is required under TSCA section 4(a) must notify EPA of each country to which a subject chemical is shipped. For chemicals subject to section 4(a), this is a one-time notification requirement (i.e., the exporter only submits the notification when it is exporting a particular chemical for the first time to a country for which it has not previously submitted a notification).

The amended HAPs proposal would therefore have an impact on exporters of HAP chemicals because the test rule would trigger TSCA section 12(b) reporting requirements. As stated earlier, this analysis considered the potential impact of the section 12(b) notification requirements on small exporters of these chemicals separately from the impacts of the testing requirements themselves.

Data on export shipments of the HAP chemicals are limited. While some data sources do present aggregate export volumes for recent years, they do not indicate the number of exporters, number of export shipments, or number of countries to which HAP chemicals are exported. For purposes of this analysis, it would be necessary to know both the number of exporters and the number of countries to which they export each HAP chemical. More specifically, because regulations promulgated pursuant to TSCA section 12(b)--40 CFR part 707-- require only a one-time notification per country, data are needed for each HAP chemical on the number of new countries that receive exported HAP chemicals in each year following promulgation of the rule. These data are not available and there is no apparent reasonable method for modeling the number of notifications.

Given this, the approach used here is to estimate the impact of the notification requirements per chemical and per country. In an analysis of the economic impacts of the July 27, 1993 amendment to the rules implementing TSCA section 12(b) (58 FR 40238), EPA estimated that the one-time cost of preparing and submitting the TSCA section 12(b) notification was $62.60.[17] Inflated through the last quarter of 1996 using the Consumer Price Index, the current cost is estimated to be $69.56. A small exporter would have to have annual revenues below $6,956 per chemical/country combination in order to be impacted at a 1 percent or greater level (see Table 2). For example, a small exporter filing 3 notifications per year would have to have annual sales revenues below $20,868 (3 x $6,956) in order to be classified as impacted at the greater than 1 percent level. EPA believes that it is reasonable to assume that few, if any, small exporters would file sufficient export notifications to be impacted at or above the 1 percent level. Based on this, the export notification requirements triggered by the proposed HAPs rule would be unlikely to have a significant economic impact on small exporters.

Because EPA has concluded that there is no significant impact on small exporters, the Agency does not need to determine the number or size of entities that would be impacted at level of a 1 percent or greater.

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[17] See *Economic Analysis in Support of the Final Rule to Amend Rule Promulgated under TSCA Section 12(b)*, William Silagi, Regulatory Impacts Branch, Office of Pollution Prevention and Toxics, June 1992.

4.0 CONCLUSION

This small entity impacts analysis confirms that the amended HAPs proposal would not have a significant economic impact on a substantial number of small entities. The worst-case estimate shows that, on a HAP chemical by HAP chemical basis, a total of 8 small manufacturers/importers (out of 365 manufacturers/importers initially burdened) may be impacted by test costs of 1 percent or greater of their sales. For these 8 manufacturers/importers whose revenues could not be determined, the size of the testing burden could not be determined and, therefore, the potential for impacts at greater than 1 percent of sales could not be ruled out. No small manufacturers/importers for whom revenue data were available would be impacted by test costs of 1 percent or greater of their sales. In this context, the rule would be unlikely to have a significant economic impact on a substantial number of small entities because the impacts of 1 percent or greater would be on fewer than 100 affected small entities. A further conclusion is that the export notification requirements triggered by the proposed rule are expected to have a negligible burden on small exporters of less than 1 percent of sales revenue. No other information available for this analysis indicates any other reason to believe that there would be a significant economic impact on a substantial number of small entities.

APPENDIX A

RELEASES OF CARBONYL SULFIDE

Appendix A. Releases of Carbonyl Sulfide

This appendix presents an analysis of the characteristics of facilities identified as releasing carbonyl sulfide in EPA's Toxics Release Inventory (TRI) and AIRS[1] Facility Subsystem (AFS) database. The first section of the appendix describes facilities identified via TRI, while the second section describes facilities identified in AFS. Because some facilities appear in both TRI and AFS, the third section characterizes the union of the two sets of facilities. Finally, the firm or parent company (hereafter, ultimate corporate entity (UCE)) level data obtained from the Dun and Bradstreet (D&B) database for the identified facilities is described.

A.I. Carbonyl Sulfide Facilities in TRI

The TRI database contains toxic chemical release and transfer information from manufacturing facilities throughout the United States. Manufacturing facilities that have the equivalent of 10 or more full-time employees and meet the established threshold for manufacturing, processing, or otherwise using listed chemicals must report their releases and transfers. Thresholds for manufacturing and processing are currently 25,000 pounds for each listed chemical, while the threshold for otherwise use is 10,000 pounds.

Based on 1995 TRI reports, 58 facilities reported on carbonyl sulfide. These facilities manufacture carbonyl sulfide as a byproduct or impurity, and they release carbonyl sulfide as fugitive or non-point source emissions or as stack or point source air emissions totaling about 17.6 million pounds. One of the 58 facilities also ships 16,000 pounds of carbonyl sulfide off-site for treatment. None of the facilities release carbonyl sulfide to any other media (e.g., land disposal, water releases, transfers to publicly owned treatment works, or underground injection). Table A.1 summarizes the TRI releases of carbonyl sulfide for 1995, the latest year for which data are available.

Facilities were classified into those releasing or transferring at least 1,100 pounds per year of carbonyl sulfide, and those releasing or transferring less than that amount. Forty-four facilities (75.9%) released or transferred at least 1,100 pounds in 1995, while 14 (24.1%) released or transferred less than that amount. These 14 facilities accounted for only 0.062 percent of all reported releases and transfers of carbonyl sulfide in 1995.

Facilities can report up to six Standard Industrial Classification (SIC) codes on a TRI form. These codes indicate the particular industrial activities undertaken at a facility that emits carbonyl sulfide. The first SIC code of the most recent form submitted by a facility is considered its primary SIC code. Ten unique primary SIC codes were reported by the facilities. Table A.2 lists these primary SIC codes and their frequency of occurrence.

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[1] Aerometric Information Retrieval System

Table A.1 1995 TRI Releases of Carbonyl Sulfide (58 facilities)			
	Air Releases (pounds)	Off-Site Transfers (pounds)	Total Releases and Transfers (pounds)
Minimum	0	0	0
Mean	303,150	276	303,430
Median	99,045	0	99,045
Maximum	2,900,000	16,000	2,900,000
Total	17,583,000	16,000	17,599,000
Notes: Three facilities filed a 1995 data collection form for carbonyl sulfide, but reported zero releases and transfers. Only one facility reported a non-zero off-site transfer amount.			

Table A.2 Primary SIC Codes Reported by Facilities Releasing or Transferring Carbonyl Sulfide			
SIC Code	**Description**	**Number of Facilities**	**Frequency**
2895	Carbon black	19	33 %
3334	Primary aluminum	11	19 %
2816	Inorganic pigments	10	17 %
2911	Petroleum refining	6	10 %
2821	Plastic materials and resins	4	7 %
3296	Mineral wool	3	5 %
2812	Alkalines and chlorines	2	3 %
2819	Industrial inorganic chemicals, n.e.c.[2]	1	2 %
3339	Primary non-ferrous metals, n.e.c.	1	2 %
3341	Secondary non-ferrous metals	1	2 %
Total	----	58	100 %

[2] not elsewhere classified

A total of eighteen unique SIC codes were reported by the 58 facilities in the 1995 TRI report, when all SIC codes are considered. Table A.3 provides the listing of all SIC codes reported.

The list of total SIC categories and the list of primary SIC categories present very similar pictures of industry activities. The first six SIC codes on Table A.3 are also on Table A.2. In several cases, the secondary SIC codes are closely related to SIC codes on the primary list. For example, the total list includes aluminum sheet, plate and foil (SIC 3353), aluminum rolling and drawing, not elsewhere classified (SIC 3355) and aluminum extruded products (SIC 3354), in addition to primary aluminum (SIC 3334), which is on the primary SIC code list.

Table A.3
All SIC Codes Reported by TRI Facilities Releasing or Transferring Carbonyl Sulfide

SIC Code	Description	Number of Mentions	Frequency of Mention
2895	Carbon black	19	25 %
3334	Primary aluminum	11	14 %
2816	Inorganic pigments	10	13 %
2821	Plastic materials and resins	6	8 %
2911	Petroleum refining	6	8 %
2819	Industrial inorganic chemicals, n.e.c.	4	5 %
2869	Industrial organic chemicals, n.e.c.	4	5 %
2812	Alkalines and chlorines	3	4 %
3296	Mineral wool	3	4 %
3353	Aluminum sheet, plate and foil	2	3 %
3355	Aluminum rolling and drawing, n.e.c.	2	3 %
2813	Industrial gases	1	1 %
2822	Synthetic rubber	1	1 %
2865	Cyclic crude and intermediates	1	1 %
2873	Nitrogenous fertilizers	1	1 %
3339	Primary non-ferrous metals, n.e.c.	1	1 %
3341	Secondary non-ferrous metals	1	1 %
3354	Aluminum extruded products	1	1 %
Total	----	77	100 %*

* Does not equal 100% due to rounding.

A.II. Carbonyl Sulfide Facilities in AFS

The AIRS Facility Subsystem (AFS) is a facility-level database component of EPA's Aerometric Information Retrieval System. AFS is maintained by EPA's Office of Air Quality Planning and Standards. AFS includes general facility information as well as data on the facilities' air permits, compliance history, and estimated emissions of "criteria" pollutants and hazardous air pollutants.

Facilities report their emissions to their State agencies, who in turn file the data in AFS, although some States update data more often than others. States are required to report to EPA on annual emissions estimates for point sources emitting greater than or equal to 100 tons per year of volatile organic compounds (VOCs), nitrogen dioxide (NO2), sulfur dioxide (SO2), particulate matter less than 10 microns in size (PM-10); 1000 tons per year of carbon monoxide (CO); or 5 tons per year of lead (Pb). States are also required by the Clean Air Act Amendments to report emissions data for point sources in areas where air pollution exceeds federal standards. Facilities are generally required to report emissions every five years, on a rolling basis.

Facilities with carbonyl sulfide emissions were identified in two ways. First, facilities reporting carbonyl sulfide to the AFS were identified by the CAS number for carbonyl sulfide. Four AFS facilities report emissions of carbonyl sulfide.

Additional facilities were identified using a second method. Carbonyl sulfide is a component of some volatile organic compound (VOC) emissions. EPA has developed a "speciate" program, which classifies VOCs by their constituent chemicals and specific physical processes, called source category classifications (SCCs). This "speciate" program was used to identify the four SCCs that are associated with the release of carbonyl sulfide. These four SCCs are all part of carbon black manufacturing, and each process is estimated to release carbonyl sulfide as 8.9 percent of the total VOC-related emission from the SCC. Therefore, facilities were retrieved from AFS that reported VOC emissions from any one of these four SCCs. The estimated carbonyl sulfide emissions are then calculated to be 0.089 times the estimated VOC releases. Sixteen facilities were identified using this approach, none of which were identified in the direct AFS query for the CAS number associated with carbonyl sulfide. While each of these 16 facilities report using one or more of these 4 "carbon black" processes, the facilities may classify themselves in a non-carbon black SIC code depending on the majority of their production.

AFS data for facilities is not available for every year. In this analysis, the most recent available report is used. Of the 20 carbonyl sulfide-producing facilities located, one reported for 1996, five for 1995, two each for 1994 and 1993, one for 1992, six for 1990, and three for 1985. The 20 facilities report aggregate estimated carbonyl sulfide emissions of about 3 million pounds per year. Table A.4 provides descriptive statistics on the emissions.

Table A.5 presents the SIC codes associated with the facilities found in AFS. As was true with the facilities identified from TRI, most facilities that emit carbonyl sulfide are classified in SIC code 2895, carbon black. Fifteen percent of the facilities are in SIC code 4953, refuse systems, which is not a TRI reportable SIC code. These facilities are indicated in AFS as being landfills.

The AFS data include secondary and tertiary SIC code fields. The only secondary SIC code not previously reported as a primary is SIC code 1221, bituminous coal and lignite, surface. This is also not an industry that is currently reportable to TRI. No tertiary SIC codes were included that are not also primary SIC codes of these facilities.

In comparison to the SIC code information from TRI, no AFS facilities indicated an SIC code corresponding to primary aluminum or inorganic pigments. These two industries were among the top three reported as both the primary SIC code and as among any SIC codes in TRI.

Table A.4
AFS Emissions of Carbonyl Sulfide (20 facilities, various years)

	Emissions (pounds per year)
Minimum	0
Mean	150,600
Median	15,740
Maximum	1,057,000
Total	3,013,000
Notes: Three facilities estimated emissions as zero.	

Table A.5
Primary SIC Codes Reported by AFS Facilities Emitting Carbonyl Sulfide

SIC Code	Description	Number of Facilities	Frequency
2895	Carbon black	12	60 %
4953	Refuse systems	3	15 %
3624	Carbon and graphite products	2	10 %
2819	Industrial inorganic chemicals, n.e.c.	1	5 %
2911	Petroleum refining	1	5 %
3297	Non-clay refractories	1	5 %
Total	----	20	100 %

A.III. Combining TRI and AFS data

Seven facilities were identified in both the TRI data and AFS data, based on facility identifiers and address/geographic information. In addition, three facilities have similar address information but different facility names; these three are believed to have been acquired or otherwise changed ownership. For the facilities in common to both databases, the estimated emissions in AFS can be quite different from the TRI releases. This can be true because, in cases where carbonyl sulfide is not directly reported, AFS uses representative plant data to estimate the percentage of VOC emissions that are carbonyl sulfide. In other words, any facility releasing VOCs estimates its particular VOC emissions rate. Using the representative percentage of 8.9 percent for these processes, EPA estimates facility-specific carbonyl sulfide emissions were estimated. The particular facilities may have actual carbonyl sulfide emission percentages above or below the representative plant percentage. Because of the uncertainty involved in AFS emissions data and the age of the AFS submissions, the TRI data is considered to be more accurate for those facilities in common.

Discarding the AFS emissions data in common (the seven facilities in common plus the three believed to be in common) yields 10 facilities with emissions totaling about 670,000 pounds per year. When combined with the TRI release data, there are 68 facilities emitting or releasing about 17.9 million pounds per year of carbonyl sulfide.

A.IV. UCE Revenues

Data from the Dun and Bradstreet (D&B) registry database were used to determine the size of UCEs owning carbonyl sulfide facilities, based on UCE revenues.[3] The TRI database contains fields for facility D&B number (DUNS) and UCE DUNS, while the AFS database contains a field for facility DUNS. These fields were linked to D&B data to retrieve the UCE revenue data.

Forty-nine of the 58 TRI facilities have DUNS data; 38 of these were found in the current D&B database. Thirteen of the 20 AFS facilities have DUNS data; nine of these were found in the D&B database. An automated search was performed in the D&B database to retrieve data for those DUNS that were in the database. The 31 facilities that either have no DUNS data or have DUNS data that are not in the D&B database were manually linked to D&B UCEs via address information.

All told, there are 68 unique facilities: 58 from TRI plus 20 from AFS less ten facilities in common. These 68 facilities are associated with 37 UCEs. It was possible to link every facility to a UCE, and all UCEs have revenue data. Table A.6 summarizes descriptive statistics on revenues and carbonyl sulfide releases and emissions of the 37 UCEs.

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[3] *Dun's Marketing Information Services*, April 1997 version, accessed through EPA "Finds" system located on the Agency's mainframe computer.

Table A.6 UCE Revenues of Facilities Emitting, Releasing or Transferring Carbonyl Sulfide (37 UCEs)			
Revenues		**Releases and Emissions (lb. / yr)**	
Minimum	< $4 million	Minimum	0
Mean	$ 6.9 billion	Mean	485,000
Median	$ 940 million	Median	70,700
Maximum	>$50.0 billion	Maximum	5.20 million
Number < $40 million	5 (13.5 %)	Number < 1,100 lb. / yr.	13 (35.1%)

Of the 37 UCEs, 13 release or emit fewer than 1,100 lb per year and would not be initially burdened by the HAPs test rule. Of the 24 UCEs that are initially burdened, only two have sales below $40 million. In each case, they generate more than 100,000 pounds of the chemical and therefore are not considered to be small businesses under the TSCA definition (40 CFR 704.3). Thus, there are no initially burdened small UCEs that generate carbonyl sulfide.

Table A.7 lists the UCEs and their emissions of carbonyl sulfide.

Table A.7 Emissions of Carbonyl Sulfide	
UCE Name	**Emissions (lbs)**
American Carbide Co.	0
Ucar Carbon Co.	0
Uno-ven	0
Owens Corning	0
Talley Industries	4
Lion Oil Co.	30
Ashland Petroleum Co.	33
Montana Sulphur and Chemical	250
NAC Carbon	338
Elf Aquitaine	356
Morganite North America	475
General Electric Co.	752
WMX Technologies, Inc.	1,020
Dow Chemical Co.	1,100
USA Waste Services	4,920
Titanium Metals Corp.	5,300
Louisiana Pigment Co., LLP	18,700
Kerr-McGee	64,000
3M Company	70,700
Chevron Chemical Corp.	71,430
Citgo Petroleum	75,000
Witco	91,786
GVC Holdings Inc.	93,649
Goldendale Aluminum	97,090
Rock Wool Mfg. Co.	122,658
Vanalco	250,000
Sid Richardson Carbon Co.	251,790
Refined Metals Corp.	256,320
Walter Industries, Inc	260,505
Kemira Holdings Inc.	300,000
Degussa Corp.	655,233
Columbian Chemicals Co.	919,546
Cabot Corp.	1,335,307
Alumax Inc.	1,434,598
Alcoa Inc.	3,163,243
E I du Pont de Nemours	3,190,400
SCM Chemical	5,200,016
Sources: Emissions from 1995 TRI and various years of AFS.	

APPENDIX B

ESTIMATING THE TESTING COSTS

B.I. Introduction

In support of the proposed HAPs test rule, EPA prepared an economic analysis of the testing requirements described in the proposed rule based on the costs of performing tests under test guidelines that were in effect in 1995.[1] Since that time, eleven new TSCA test guidelines were added to part 799 of title 40 of the Code of Federal Regulations.[2] These series 799 test guidelines were developed from the public draft versions of the OPPTS harmonized test guidelines 870 series[3] and are cross-referenced in the amended HAPS proposal (upcoming Federal Register publication).

This appendix provides additional information describing how EPA estimated the costs of testing each of the 21 HAP chemicals using eleven TSCA 799 test guidelines.

This appendix contains the following sections: "Methods," which describes the approach used to obtain the cost estimates and "TSCA 799 Test Guideline Costs" which contains tables listing the cost estimates for each type of test and each chemical. The estimated costs for toxicity tests required by the amended HAPs proposal are summarized in Tables B.1 and B.2, which present both test-specific and chemical-specific costs. Test cost data are provided as three estimates for each test: best, minimum and maximum.[4] Detailed tables with cost adjustment data and test guideline information are provided as supplementary information at the end of this appendix in Tables B.3 and B.4.

B.II. Methods

The amended HAPs proposal requires testing of HAPs chemicals using health effects test guidelines for acute inhalation toxicity with histopathology, subchronic inhalation toxicity, prenatal inhalation toxicity, reproduction and fertility effects toxicity, carcinogenicity, four tests for genetic toxicity, neurotoxicity, and immunotoxicity. The TSCA 799 series of health effect guidelines is the most recent effort by EPA to reflect the state-of-the-art for toxicity testing.

Prior to the publication of the eleven TSCA 799 series guidelines, EPA used draft versions substantially similar to the final guidelines to estimate costs of performing toxicity testing using these guidelines. Multiple changes in test guidelines are incorporated in the transition from the earlier test guideline series (795, 798, and 870) to the current TSCA 799 series.

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[1] *Section 4 Test Rule Support for 21 Hazardous Air Pollutants, non-CBI version,* EPA/OPPT/EETD/RIB with the support of Mathtech, Inc., April 4, 1995.

[2] 62 FR 43820, August 15, 1997.

[3] 61 FR 31522, June 20, 1996.

[4] All manipulations and calculations discussed in subsequent sections were made to each of the three estimates, although the discussion uses the general term "cost" for simplicity of presentation.

The development of the test cost estimates for the TSCA 799 Series guidelines has three basic steps:

Step 1: Identify the most similar guideline for which a cost estimate is available

Step 2: Compare the TSCA 799 guideline to the most similar guideline for which a cost estimate is available to determine if adjustments are necessary

Step 3: Adjust the available cost estimate to obtain a cost estimate for the TSCA 799 guideline

B.II.1. Basic Cost Data

The principal elements of the total laboratory cost estimate[5] for each toxicity test are total direct labor, overhead, other direct costs, general and administrative (G&A) costs and fee (as described below).

Direct Labor. To determine total direct laboratory labor, the test guidelines are reviewed and summarized in an outline of the study protocol. The usual time required to complete each task in the protocol is estimated and the job category required for the task is determined. Total labor hours for each job category are multiplied by the hourly rate for the category to determine total labor costs. Salary rates are based on estimates of industry averages obtained from multiple sources.

Overhead. The overhead rate is applied as a percentage of total direct labor to cover the costs incurred by a laboratory in facility operation, fringe benefits, and indirect labor. Data from government contract bids and other sources were used in estimating this cost element.

Other Direct Costs. These include laboratory and related supplies, subcontracted services, and overtime costs. Standard costs for items were used along with costs for specialized services that require outsourcing (e.g., opthomological examinations required intermittently), and overtime required due to the 7 day-per-week, 24 hour-per-day operation of a laboratory.

General and Administrative (G&A) Services. Costs for salaries to cover activities such as accounting, personnel, purchasing, payroll, legal services, and marketing are included in this cost element. These are less variable than overhead costs and average 15 percent in most businesses.

Fee. Fees vary markedly. The variability is determined by such factors as capacity, capabilities, test duration, test type, and current market conditions.

Cost Range. The cost range is calculated by substituting the lowest and highest expected overhead rates into the total cost calculation. Overhead is used as the main variable because it is the most significant cost component in the overall test cost and can vary greatly from company to company and within specific departments within a company.

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[5] Cost estimates for past test guidelines were developed by EPA under contract No. 68-W6-0022. Detailed information on guideline cost estimates is available in "TSCA Test Guidelines: Cost Estimates for Health Effects Testing" (OPPT/EETD/RIB various dates) which is available in the public record for this rulemaking.

Best Estimate. The best estimate is based on professional judgement and is usually the midpoint of the cost estimate range.

B.II.2. Adjustments

Types of Adjustments

To obtain cost estimates for the toxicity tests required by the amended HAPs proposal, various adjustments were made to modify the available cost information. This was necessary because cost estimates were not always available for the species or route of exposure of interest. Adjustments were also necessary to account for inflation, in cases where the test estimates were made prior to 1996. A description of general adjustments that were made to the available cost estimates is given below. This is followed by a description of the specific adjustments required to calculate the costs for each type of test.

Inflation Adjustments

For all data more than one year old, cost estimates were adjusted for inflation through 3/31/97 using the GDP Implicit Price Deflator.

Scaling Adjustments

Many test costs were "scaled" using a multiplier derived from available cost estimates to determine estimated costs for the species and routes of exposure required in the amended HAPs proposal. This was done by reviewing the available estimates for species and routes of exposure to determine the ratio of costs between tests with the species and exposure routes of interest. This ratio was used as a multiplier to derive estimated costs for those not available. For example, cost estimates were not available for the four-hour neurotoxicity assays in rats via the inhalation route, as specified in the amended HAPs proposal. However, cost estimates were available for the four-hour neurotoxicity assay in rats exposed via gavage test. Cost estimates on both gavage and inhalation were available for chronic toxicity, oncogenicity, and combined chronic and oncogenicity tests (guidelines 870.4100, 870.4200, and 870.4300). The ratios of the inhalation/gavage costs for these three guidelines are 1.19, 1.27. and 1.52, respectively, and the average ratio is 1.33. This average ratio was considered reasonably representative of the inhalation/gavage cost ratio. To obtain the final four-hour neurotoxicity cost estimate for exposure via inhalation, the ratio (1.33) was multiplied by the cost estimate for a gavage study (1.33 x gavage cost = inhalation test estimate).

In cases where scaling was carried out, tests were selected as the source of ratios because they matched as closely as possible to the type, duration, exposure, and the nature of the required test. A specific example of this is the scaling of the *in vivo* bone marrow test costs that was carried out using the similar *in vivo* erythrocyte test cost estimate. Although there are small differences in test protocols and duration, the application of scaling factors in this manner is a relatively accurate approach to cost estimation.

Averaging Adjustments

In cases where a general test description was provided in the amended HAPs proposal, and only specific cost estimates were available, the average cost of the specific tests was calculated and used as representative of the general test type. For example, when an inhalation exposure route was specified and only costs for the specific inhalation phases (e.g., vapor and aerosol) were available, the average cost for the two phases was calculated to obtain an average value for the inhalation test. The average is listed as the cost estimate. When multiple species were required or allowed (e.g., with regard to the developmental toxicity and carcinogenicity tests) an average cost for the two or three species having cost data was also provided.

Test-specific Cost Modifications

The following section describes the procedure used to estimate costs for performing each of the eleven TSCA 799 test guidelines, identifies the substantive differences between available cost estimates and required test guidelines, and identifies adjustment factors applied. This discussion, including the exact source of available cost estimates, is summarized in Table B.3.

See Table B.1 for the estimated costs of each of the tests required in the amended HAPs proposal and Table B.2 for the chemical-specific costs of tests required in the amended HAPs proposal.

Acute Inhalation Toxicity Test and Acute Test Modification (799.9135)

Test cost estimates were available for the acute toxicity test via the correct route of exposure and in an acceptable species. Consequently, scaling was not necessary. The cost estimates were adjusted for inflation as described above. For this test, an inhalation exposure route was specified and only costs for the specific inhalation phases (e.g., vapor and aerosol) were available. The average cost for the two phases were calculated to obtain a representative value for the test. The average is listed in row three of Table B.3 for the cost estimates (best, best adjusted, etc.)

Neurotoxicity Screen (799.9620)

The neurotoxicity screening cost estimates for both the 4-hour and 90-day tests were made in 1997 and therefore did not need to be adjusted for inflation. However, cost estimates for the 4-hour test were available only for gavage exposure, and 90-day test cost estimates were available only for dietary exposure. Both required scaling to obtain a cost estimate for the inhalation route of exposure specified in the regulations.

4-hour test

The 4-hour test cost estimates were multiplied by a derived scaling factor (1.33) to obtain the estimated costs for inhalation exposure. The value of 1.33 was obtained from a review of the relationships between the costs of the gavage and inhalation exposure routes for three tests for which cost data were available for both routes of exposure: chronic toxicity, oncogenicity, and combined chronic and oncogenicity (guidelines 870.4100, 870.4200, and 870.4300). The ratios of the costs (inhalation costs/gavage costs) for these three tests is 1.19, 1.27, and 1.52, respectively, and the average cost ratio is 1.33.

Example using the "best cost estimate":

The best estimate of the cost of the 4-hour test via gavage is $77,040. This value was multiplied by 1.33 to obtain the cost adjusted for the inhalation route of $102,463. This is listed in Table B.3 as the "best" adjusted cost.

90-day test

There were no relevant cost estimates available for the 90-day test regarding the ratio between dietary exposure and inhalation exposure tests. Consequently, a two-step process was required to obtain a cost estimate for the 90-day neurotoxicity test for the inhalation route, because only dietary data were available. The dietary to gavage ratios were calculated first, followed by application of the gavage to inhalation ratio discussed in the paragraph above. Guidelines 870.6300, 870.7800, and 870.3100 with cost ratios of 1.006, 1.036, and 1.07 were used as the basis for the dietary to gavage ratio, yielding an average ratio of 1.037. The test cost estimate for the dietary 90-day neurotoxicity assay was multiplied by this value to obtain an estimate of the cost for a gavage test. Then the multiplier for the gavage to inhalation ratio (1.33, described in the paragraph above) was multiplied by the value obtained in the estimated gavage cost (the cost obtained in the first step), to obtain the final inhalation cost estimate.

Example using the "best cost estimate":

The 90-day dietary test cost of $112,110 was multiplied to 1.037 and then by 1.33 to obtain a cost estimate for the 90-day test via the inhalation route of $168,512, which is listed as the best adjusted cost estimate in Table B.3.

Combined test cost assumption

The neurotoxicity test requirement specifies that a short-term test be carried out, and, depending on the results obtained, a subchronic test may be required. It was assumed for the cost estimates that both tests would be carried out. This provides an estimate of the maximum (or worst case) costs that may be incurred for this test group.

Subchronic Test and Subchronic Test Modification (799.9346)

Test cost estimates for the subchronic toxicity test via the inhalation route were made in 1997. Consequently, there was no adjustment required for the basic test. However, there are no cost estimates available for the modifications required under these proposed regulations that specify respiratory system lavage and pathological evaluation. To obtain an estimate of the costs, a review of the testing requirements under this modification was made. The requirement to carry out lavage and pathological evaluation are in addition to numerous other types of pathological evaluations and tissue preparation specified in the standard subchronic test guideline. Taking this information into account, it was estimated that the additional requirements, beyond the basic test activities, would increase the cost of the test by approximately 20 percent. The total costs listed for this test reflect the sum of the basic test plus the test modification.

Developmental Toxicity Test (799.9370)

Estimating the cost of the developmental toxicity test requirement is complex because multiple species are required for many chemicals and the cost data available for each species varies. An average cost was calculated for the developmental toxicity test because the testing of two species of mammals are required for some chemicals. Both mouse and rat cost estimates are available via the correct route of exposure (inhalation) and were used in the cost estimate. However, mouse or rat tests are excluded in the proposed rule for some chemicals; consequently, a third species was needed. Rabbit cost estimates were available and used in this analysis. To obtain an average cost for multiple species, first adjustments for inflation were made to cost estimates for each of the three species to standardize the basis for averaging. Because both rat and mouse cost estimates required inflation adjustments (they were from 1994 and 1995), all three of the species cost estimates were adjusted through the first quarter of 1997, even though the rabbit cost estimates are less than one year old. This was done in order to provide a consistent basis for averaging the three estimates. In all cases the cost estimates were modified for inflation as described above.

The second step was to obtain estimates for each of the three species exposed via the inhalation route. Inhalation exposure cost data were available for both the mouse and rat, so scaling was not required. However, cost estimates for mice were available for only specific phases of inhalation exposure: vapor and aerosol. Consequently, the average of these two estimates were calculated to obtain an average estimate for the inhalation exposure test cost for mice.

Estimates for rabbit inhalation test costs were not available, and scaling was required from test cost estimate for the gavage route of exposure. No cost estimates were available for rabbits exposed by both the gavage and inhalation exposure routes, so a ratio could not be calculated directly from rabbit test cost estimates. The scaling factor obtained from the ratio of test costs for rats exposed via gavage and inhalation was used to scale the test cost estimates for rabbits. It is reasonable to assume that the ratios for these two mammalian species are similar (1.33). The derivation of this ratio is described above in the neurotoxicity screen discussion above.

To obtain an average test cost for conducting tests in two species, the costs for the three species were summed and multiplied by 2/3 (multiplied by 1/3 to obtain an average value and multiplied by 2 to obtain costs for 2 species).

Example using the "best cost estimate":

The sum of the inflated cost for the rat of $86,560, the inflated and averaged cost for the mouse of $87,800, and the scaled and inflated cost for the rabbit of $161,729, was calculated and yielded a total cost estimate of $336,089. Two thirds of this cost is $224,060, which is the final "best" estimate of the cost for the test when two species are required to be tested.

Reproductive Test (799.9380)

The reproductive toxicity test costs were estimated within the last year, so no inflation adjustment was necessary. The test cost estimates were for exposure via gavage. Consequently a scaling factor of 1.33 (as described in the neurotoxicity screen discussion above) was applied to the gavage cost estimate to obtain a cost estimate for the inhalation route of exposure.

Carcinogenicity Test (799.9420)

The carcinogenicity toxicity test costs were estimated within the last year, so no inflation adjustment was necessary. The costs for carcinogenicity tests are based on either:

1) a requirement that a male rat and female mouse are used, or

2) no species requirement.

In the first case, a "blended" cost was calculated using the sum of ½ of the rat test cost and ½ of the mouse test cost (in effect the average of the two test costs). In the second case, use of the average cost for mice and rats (the two species for which cost estimates are available) was used to estimate the test costs. This value is the same as the blended value ([mouse+rat]/2).

Immunotoxicity Test (799.9780)

The immunotoxicity test costs were estimated within the last year, so no inflation adjustment was necessary. The test cost estimates were available for rats exposed via gavage. As no species was specified in the proposed rule, the rat cost estimates were used as representative of the costs for this test. To obtain an inhalation cost estimate, a scaling factor of 1.33 was applied to the gavage cost estimates for the rats.

***In Vivo* Bone Marrow Test** (799.9538)

The *in vivo* bone marrow test costs were estimated within the last year, so no inflation adjustment was necessary. Test cost estimates were for rats exposed via gavage. As no species requirement was listed in the proposed rule, the rat data were used as representative of the costs of this test. Scaling was required, however, to obtain a cost estimate for inhalation exposure. Scaling data were obtained from a similar type of test: the *in vivo* erythrocyte test (870.5395). A comparison of the gavage and inhalation routes of exposure for this test yielded a ratio of 1.1. This ratio was multiplied by the gavage test cost data for the bone marrow test to obtain adjusted estimate of the test cost.

***In Vivo* Erythrocyte Test** (799.9539)

The *in vivo* erythrocyte test costs were estimated within the last year, so no inflation adjustment was necessary. Test cost estimates were available for two time periods: 1- and 3-day tests in rats. As no species requirement was listed in the proposed rule, the rat cost estimates were used as representative of the costs for this test. The average of these two test costs was calculated to obtain the estimated average cost.

Mutation Somatic Cell Culture (799.9530)

The mutation somatic cell culture test costs for the appropriate type of tests (C.O. and mouse) were estimated in 1994 and therefore required adjustment for inflation. The costs for the two types of tests are the same, and a single inflated set of cost estimates are reported.

E. Coli - **Mutation Test** (799.9510)

The *E. coli* mutation test costs were estimated within the last year, so no inflation adjustment was necessary. The *E. coli* test requirement is a modification of an older test requirement that specified five cell mutation assays be carried out. The original guideline focused on salmonella testing; the new requirements specify that one of the five tests be carried out on *E. coli*. It is not anticipated that this change in bacterial species will alter the test costs significantly. Consequently, the test costs for salmonella were used to estimate the test costs for the revised guideline with the *E.coli* requirement. Both Azo and direct plate Salmonella testing costs were provided in earlier cost estimates and were very similar. The average of the costs for the two test types was used as the cost estimate for this test requirement.

B.III TSCA 799 Series Guideline Costs

This section contains summary tables of cost data organized by test and by chemical. Table B.1 summarizes the cost estimates for each type of test. Test costs were estimated as described in the preceding "Methods" section. (A table providing supplementary information to Table B.1, and containing summaries of the adjustments to the cost estimates is provided at the end of this section in Table B.3.)

TABLE B.1 - Estimated Laboratory Costs of Toxicology Tests Required in Amended HAPs Proposal

Test Description	TSCA 799 Series Guideline (40 CFR)	Laboratory Test Costs		
		Best	Min	Max
Acute Inhalation Toxicity with Acute Modification	799.9135 with (ASTM E 981-84)	70,029	56,940	84,149
Neurotoxicity Screen	799.9620	270,975	218,741	327,748
Subchronic with Subchronic Modification	799.9346	328,440	193,488	466,836
Developmental	799.9370	224,060	177,198	273,800
Reproductive	799.9380	566,221	426,092	765,601
Carcinogenicity	799.9420	763,930	611,020	994,590
Immunotoxicity	799.9780	73,137	52,801	96,412
In Vivo Bone Marrow	799.9538	38,302	31,460	45,705
In Vivo Erythrocyte	799.9539	13,915	11,150	16,855
Mutation Somatic Cell Culture	799.9530	16,066	12,766	19,641
E. Coli - Mutation	799.9510	5,905	4,420	7,460

Table B.2 contains laboratory test cost estimates for each chemical. It lists the costs for each type of test required under the amended HAPs proposal, using costs shown in Table B.1 and the total costs for each chemical. (A table providing supplementary information to Table B.2, and containing summaries of the cost adjustments is provided at the end of this section in Table B.4.

Table B.2: Chemical-specific Laboratory Costs of Tests Required in Amended HAPs Proposal					
CAS Number	HAP Chemical	Protocol Title	Cost		
			Best	Min.	Max.
79-00-5	1,1,2-Trichloroethane	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Carcinogenicity	763,930	611,020	994,590
		In Vivo Bone Marrow	38,302	31,460	45,705
		In Vivo Erythrocyte	13,915	11,150	16,855
		Immunotoxicity	73,137	52,801	96,412
		Total	**2,349,008**	**1,778,890**	**3,071,696**
120-82-1	1,2,4-Trichlorobenzene	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Developmental	224,060	177,198	273,800
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**638,200**	**505,680**	**782,109**
92-52-4	1,1'-Biphenyl	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**1,532,861**	**1,125,260**	**2,014,546**
463-58-1	Carbonyl Sulfide	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Carcinogenicity	763,930	611,020	994,590
		E. Coli Mutation	5,905	4,420	7,460
		Mutation-Somatic Cell Culture	16,066	12,766	19,641
		In Vivo Bone Marrow	38,302	31,460	45,705
		In Vivo Erythrocyte	13,915	11,150	16,855
		Immunotoxicity	73,137	52,801	96,412
		Total	**2,370,979**	**1,796,076**	**3,098,797**
7782-50-5	Chlorine	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Total	**70,029**	**56,940**	**84,149**
108-90-7	Chlorobenzene	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**742,581**	**521,970**	**975,145**
126-99-8	Chloroprene	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**980,362**	**754,574**	**1,273,910**
95-48-7	Cresol, ortho-isomer	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**742,581**	**521,970**	**975,145**
106-44-5	Cresol, para-isomer	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**742,581**	**521,970**	**975,145**

Table B.2: Chemical-specific Laboratory Costs of Tests Required in Amended HAPs Proposal					
CAS Number	HAP Chemical	Protocol Title	Cost		
			Best	Min.	Max.
108-39-4	Cresol, meta-isomer	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**742,581**	**521,970**	**975,145**
111-42-2	Diethanolamine	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**1,532,861**	**1,125,260**	**2,014,546**
100-41-4	Ethylbenzene	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**1,204,421**	**931,772**	**1,547,710**
107-06-2	Ethylene Dichloride	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Total	**1,459,725**	**1,072,459**	**1,918,134**
107-21-1	Ethylene Glycol	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**742,581**	**521,970**	**975,145**
7647-01-0	Hydrochloric Acid	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Total	**70,029**	**56,940**	**84,149**
7664-39-3	Hydrogen Fluoride	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**1,532,861**	**1,125,260**	**2,014,546**
108-31-6	Maleic Anhydride	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Developmental	224,060	177,198	273,800
		Neurotoxicity Screen	270,975	218,741	327,748
		Carcinogenicity	763,930	611,020	994,590
		Immunotoxicity	73,137	52,801	96,412
		Total	**1,402,130**	**1,116,700**	**1,776,699**
108-10-1	Methyl Isobutyl Ketone	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Reproductive	566,221	426,092	765,601
		Immunotoxicity	73,137	52,801	96,412
		Total	**709,387**	**535,833**	**946,162**
80-62-6	Methyl Methacrylate	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Immunotoxicity	73,137	52,801	96,412
		Total	**1,204,421**	**931,772**	**1,547,710**

Table B.2: Chemical-specific Laboratory Costs of Tests Required in Amended HAPs Proposal					
CAS Number	HAP Chemical	Protocol Title	Cost		
			Best	Min.	Max.
91-20-3	Naphthalene	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Reproductive	566,221	426,092	765,601
		Immunotoxicity	73,137	52,801	96,412
		Total	**709,387**	**535,833**	**946,162**
108-95-2	Phenol	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Immunotoxicity	73,137	52,801	96,412
		Total	**143,166**	**109,741**	**180,561**
85-44-9	Phthalic Anhydride	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Subchronic	328,440	193,488	466,836
		Developmental	224,060	177,198	273,800
		Reproductive	566,221	426,092	765,601
		Neurotoxicity Screen	270,975	218,741	327,748
		Carcinogenicity	763,930	611,020	994,590
		Immunotoxicity	73,137	52,801	96,412
		Total	**2,296,791**	**1,736,280**	**3,009,136**
75-35-4	Vinylidene Chloride	Acute Inhalation Toxicity & Modification	70,029	56,940	84,149
		Neurotoxicity Screen	270,975	218,741	327,748
		Total	**341,004**	**275,681**	**411,897**

Supplementary Information

Two tables are contained in this section that provide additional detail regarding adjustments made to determine costs for specific toxicity tests (Table B.3) and testing costs for individual chemicals (Table B.4). Narrative text is provided to explain each column in the tables, due to their complexity. The "Methods" section of this appendix explains the adjustments listed in these tables in more detail.

Table B.3 Test-Specific Cost Estimate Modifications

Test cost information for the amended HAPs proposal are listed for each type or group of tests, with the specific species and route requirements listed in from the amended HAPs test rule. The adjustments made to the cost estimates are listed in the table footnotes and described in detail in the section above titled: "Test-specific Modifications."

Column-by-column explanation of Table B.3

Test description: generic name of the test

Guidelines: Over the past several years, EPA has referred to similar test guidelines by different citation numbering systems. The guideline series citation numbers are listed in this column. The 795 or 798 series included in parts 795 or 798 of Title 40 of the Code of Federal Regulations were originally used by the Office of Toxic Substances. The 870 series guidelines refer to a "harmonized" system developed for by the Office of Prevention, Pesticides, and Toxic Substances. The part 799 series of Title 40 of the Code of Federal Regulations refers to a set of guidelines that was promulgated on August 15, 1997. While some test guidelines are identical to guidelines under previous numbering systems, others have been modified. Costs of performing tests under the eleven TSCA 799 series test guidelines to be used in the amended HAPs proposal were estimated primarily from the existing cost estimates for the 795, 798, and 870 series guidelines.

Cost Source: Existing cost estimate reports were used as the basis for all cost estimates. The test guideline that served as the basis for the cost estimate is shown first. The specific date of the estimates is shown in parentheses.

Species and Route Required and Available: The species and route required in the proposed HAPs test rule available in the cost source are shown. For example, "--/Rat" means that the species in the test rule is not specified and the species for which information was available was the rat. When these differ, it was necessary to scale the cost data to obtain appropriate cost estimates.

Other Factors: These include information that is used to define a test cost category, such as route, duration, species, etc.

Adjustment Type: Adjustments to original cost estimates were necessary for most tests due to inflation, the need to scale test data from available test cost data to the required test, or to obtain average cost values. The specific adjustments made to obtain each adjusted cost are listed in the footnotes of the table. They are also discussed for each test in the "Test-specific Modifications" section below.

Cost: The best, minimum, and maximum cost estimates are provided for each test as listed in the cost

reports. Adjusted costs are listed in the adjacent columns. The range reflects variations in testing protocols and cost differences among laboratories. The best estimate is based on professional judgement and is usually the midpoint of the range of costs.

Lab Hours: Labor hours required to perform the tests are listed. These were taken from the cost estimates listed in the "cost source" column. They are based on estimates of the laboratory time required to conduct the testing.

Totals

Total estimates within a test category are listed in the bottom row for each test. Totals were required when a test had multiple components (e.g., acute inhalation toxicity plus the modification for mouse sensitization). The adjusted totals are the final values, which have been modified, as required, by scaling, inflating, etc. In some cases, where adjustments were not required, there are no data listed in the adjustment columns. The final values are highlighted by gray boxes. These are the values used in Table B.4 to estimate the chemical-specific test costs.

Table B.3: Test-Specific Laboratory Cost Estimate Modifications

Test Description	Guidelines			Cost Source a	Species Rqd./Avail. b	Route Rqd./Avail. c	Other Factors	Adjustment Type	Cost d Best	Best Adjusted	Min.	Min. Adjusted	Max.	Max. Adjusted	Lab Hours
Acute Inhalation Toxicity	795.xx	870.1350	799.9135	795.xx (11/15/94)	--/Rat	Inhal./Inhal.	Vapor	Inflate e	57,160	60,457	46,830	49,531	68,320	72,260	693
							Aerosol	Inflate e	57,580	60,901	47,180	49,901	68,820	72,789	701
								Average f	57,370	60,679	47,005	49,716	68,570	72,525	697
Acute Modification	--	FR (ASTM E 981-84)	--	ASTM E 981-84 (12/8/94)	Mouse/Mouse	Nose Cone/ Nose Cone	None	Inflate e	8,840	9,350	6,830	7,224	10,990	11,624	109
								Total	66,210	70,029	53,835	56,940	79,560	84,149	806
Neurotoxicity Screen	N/A	870.6200	799.9620	870.6200 (9/25/96)	--/Rat	Inhal./Gavage	4-hour	Scale g	77,040	102,463	64,090	85,240	91,390	121,549	925
						Inhal./Dietary	90-day	Scale h	122,110	168,512	96,740	133,501	149,420	206,200	1,387
								Total i	199,150	270,975	160,830	218,741	240,810	327,748	2,312
Subchronic	798.2450	870.3465	799.9346	870.3465 (12/2/96)	--/Rat	Inhal./Inhal.	None	None	273,700		161,240		389,030		2,458
Subchronic Modification	--	FR	--		--/Rat	Inhal./Inhal.	None	Estimate j	54,740		32,248		77,806		492
								Total	328,440		193,488		466,836		2,950
Developmental	870.3700	870.3700	799.9370	870.3700 (4/20/94)	2 Mammalian Species/Rat, Mouse, Rabbit	Inhal./Inhal.	Rat	Inflate e	81,840	86,560	64,180	67,882	100,720	106,529	1,291
				870.3700 (8/17/94)		Inhal./Inhal.	Mouse, Vapor	Inflate e	83,480	88,295	65,430	69,204	102,850	108,782	1,361
				870.3700 (1/22/95)			Mouse, Aerosol	Inflate e	84,670	87,306	66,410	68,478	104,270	107,516	1,385
								Average	84,075	87,800	65,920	68,841	103,560	108,149	1,373
				870.3700 (8/27/96)		Inhal./Gavage	Rabbit	Scale k	120,450	160,199	96,130	127,853	145,990	194,167	1,157
								Inflate e	121,601	161,729	97,048	129,074	147,385	196,022	1,157
								Sum of 3 species	287,516	336,089	227,148	265,797	351,665	410,700	3,821
								Total l	191,677	224,060	151,432	177,198	234,443	273,800	2,547
Reproductive	870.3800	870.3800	799.9380	870.3800 (8/27/96)	--/Rat	Inhal./Gavage	None	Scale g	425,730	566,221	320,370	426,092	575,640	765,601	5,024
Carcinogenicity	798.3300	870.4200	799.9420	870.4200 (4/4/97)	Male Rat & Female Mouse Or Unspecified/ M. Rat & F. Mouse	Inhal./Inhal.	Rat	None	841,280		672,800		1,097,450		11,683
							Mouse	None	686,580		549,240		891,730		9,800
								Blend m	763,930		611,020		994,590		10,742
Immunotoxicity	798.2450	870.7800	799.9780	870.7800 (12/2/96)	--/Rat n	Inhal./Gavage	None	Scale g	54,990	73,137	39,700	52,801	72,490	96,412	415
In Vivo Bone Marrow	798.5385	870.5385	799.9538	870.5385 (9/25/96)	--/Rat	Inhal./Gavage	None	Scale o	34,820	38,302	28,600	31,460	41,550	45,705	394

Table B.3: Test-Specific Laboratory Cost Estimate Modifications

Test Description	Guidelines			Cost Source a	Species Rqd./Avail. b	Route Rqd./Avail. c	Other Factors	Adjustment Type	Cost d Best	Best Adjusted	Min.	Min. Adjusted	Max.	Max. Adjusted	Lab Hours
In Vivo Erythrocyte	798.5395	870.5395	799.9539	870.5395 (2/27/97)	--/Mouse	Inhal./Inhal.	1-day test	None	13,300		10,640		16,120		135
							3-day test	None	14,530		11,660		17,590		158
								Average	13,915		11,150		16,855		147
Mutation-Somatic Cell Culture	798.5300	870.5300	799.9530	798.5300 (8/16/94)	--/CHO,HGPRT --/Mouse, Both have same cost	N/A	N/A	Inflate e	15,190	16,066	12,070	12,766	18,570		144
E. Coli - Mutation	798.5100	870.5100	799.9510	870.5265 (9/19/96)	N/A	N/A	Azo	None	5,960		4,460		7,520		49
							Direct	None	5,850		4,380		7,400		47
								Average p	5,905		4,420		7,460		48

a) Cost Source: Guideline, (Date of Cost Estimate)

b) Species required in proposed rule is listed first, followed by the species for which cost data are available.

c) Route required in proposed rule is listed first, followed by the route for which cost data are available.

d) Highlighted cost values represent the final best, minimum, and maximum cost estimates for each test.

e) Inflation to 1997 values was conducted using the GDP Implicit Price Deflator for 1994, 1995, third FQ for 1996 and first FQ for 1997.

f) Requirements don't specify phase, so use average of aerosol and vapor phases.

g) Gavage to Inhalation: Tests 870.4100, 870.4200, 870.4300 used as basis with ratios 1.19, 1.27, and 1.52. Use Average = 1.33 as scaling factor.

h) Dietary to inhalation: No direct ratios, so use dietary to gavage, then gavage to inhalation. Tests 870.6300, 870.7800, 870.3100 used as basis with ratios 1.006, 1.036, and 1.07. Use Average = 1.037 for dietary to gavage. Then, for gavage to inhalation, multiply 1.037 * 1.33 = 1.38 (see also Footnote a) above).

i) 4-hour results may trigger 90-day test, so assume 90-day test costs always added.

j) In the absence of complete costing information, it was estimated that the additional modifications required by the proposed rule would result in costs equal to 20% of the subchronic inhalation toxicity test cost.

k) No data for scaling gavage to inhalation for rabbit, so use rat scaling factor of 1.33.

l) Take 2 out of 3 species = (Rat cost/3 + Mouse cost/3 + Rabbit cost/3) * 2.

m) Same calculation used for two scenarios: (1) Male rat and female mouse required, so blend costs: Rat cost/2 + Mouse cost/2 = x. (2) When species are not specified, use of a rat or mouse is assumed, and the average costs for the 2 species are used (same formula as blended costs).

n) Cost data were available for the rat and mouse. The costs are very similar, and the slightly higher cost of the test in rats was used in this analysis.

o) Use factor of 1.1 to scale cytogenetic bone marrow assay from gavage to inhalation. Derived from inhalation/gavage ratio of protocol 870.5395.

p) Use average of Azo reduction and direct plate costs. E. Coli can now be used as 1 of 5 assays required. Costs are similar for E. Coli and salmonella, so no change in previously estimated cost is anticipated.

Table B.4 Chemical-Specific Costs for Tests Required in Amended HAPs Proposal

Table B.4 contains chemical-specific cost data. Table B.3 is linked to Table B.4 through the use of its test categories and the final adjusted cost estimates. Chemicals are listed in order of CAS number with the required tests and additional requirements shown in the proposed test rule for each chemical. The codes used in the Special Requirement column are the same as those listed in the amended HAPs proposal and are explained in a key on the last page of the table. (The reader is referred to the amended HAPs test rule proposal for details on these specifications.) The total cost of all tests required for each chemical is shown in bold.

Table B.4: Chemical-Specific Laboratory Costs for Tests Required in Amended HAPs Proposal

CAS Number	Chemical Name	Test Description	Additional Requirements	Cost a			Laboratory Hours
				Best	Min.	Max.	
75-35-4	**Vinylidene Chloride**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Total		**341,004**	**275,681**	**411,897**	**3,118**
79-00-5	**1,1,2-Trichloroethane**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(3)	328,440	193,488	466,836	2,950
		Developmental		224,060	177,198	273,800	2,547
		Reproductive	(b)(1)(ii)(A) (b)(5)	566,221	426,092	765,601	5,024
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Carcinogenicity	(b)(1)(i)(D) (b)(1)(ii)(A)	763,930	611,020	994,590	10,742
		In Vivo Bone Marrow	(b)(1)(ii)(A)	38,302	31,460	45,705	394
		In Vivo Erythrocyte	(b)(1)(ii)(A)	13,915	11,150	16,855	147
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**2,349,008**	**1,778,890**	**3,071,696**	**25,336**
80-62-6	**Methyl Methacrylate**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Developmental	(b)(1)(i)(A)	224,060	177,198	273,800	2,547
		Reproductive	(b)(1)(ii)(A) (b)(5)	566,221	426,092	765,601	5,024
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**1,204,421**	**931,772**	**1,547,710**	**11,104**
85-44-9	**Phthalic Anhydride**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(1)(ii)(B) (b)(3)	328,440	193,488	466,836	2,950
		Developmental	(b)(1)(ii)(B)	224,060	177,198	273,800	2,547
		Reproductive	(b)(1)(ii)(B) (b)(5)	566,221	426,092	765,601	5,024
		Neurotoxicity Screen	(b)(1)(ii)(B) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Carcinogenicity	(b)(1)(ii)(B)	763,930	611,020	994,590	10,742
		Immunotoxicity	(b)(1)(ii)(B)	73,137	52,801	96,412	415
		Total		**2,296,791**	**1,736,280**	**3,009,136**	**24,795**
91-20-3	**Naphthalene**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Reproductive	(b)(1)(ii)(A) (b)(5)	566,221	426,092	765,601	5,024
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**709,387**	**535,833**	**946,162**	**6,245**

Table B.4: Chemical-Specific Laboratory Costs for Tests Required in Amended HAPs Proposal

CAS Number	Chemical Name	Test Description	Additional Requirements	Cost a			Laboratory Hours
				Best	Min.	Max.	
92-52-4	1,1'-Biphenyl	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(1)(ii)(B) (b)(3)	328,440	193,488	466,836	2,950
		Developmental	(b)(1)(i)(A) (b)(1)(ii)(B)	224,060	177,198	273,800	2,547
		Reproductive	(b)(1)(ii)(B) (b)(5)	566,221	426,092	765,601	5,024
		Neurotoxicity Screen	(b)(1)(ii)(B) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(B)	73,137	52,801	96,412	415
		Total		**1,532,861**	**1,125,260**	**2,014,546**	**14,054**
95-48-7	**Cresols** ortho-isomer	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(3)	328,440	193,488	466,836	2,950
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**742,581**	**521,970**	**975,145**	**6,483**
106-44-5	**Cresols** para-isomer	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(3)	328,440	193,488	466,836	2,950
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**742,581**	**521,970**	**975,145**	**6,483**
108-39-4	**Cresols** meta-isomer	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(3)	328,440	193,488	466,836	2,950
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**742,581**	**521,970**	**975,145**	**6,483**
100-41-4	**Ethylbenzene**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Developmental	(b)(1)(i)(A)	224,060	177,198	273,800	2,547
		Reproductive	(b)(1)(ii)(A) (b)(5)	566,221	426,092	765,601	5,024
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**1,204,421**	**931,772**	**1,547,710**	**11,104**

Table B.4: Chemical-Specific Laboratory Costs for Tests Required in Amended HAPs Proposal

CAS Number	Chemical Name	Test Description	Additional Requirements	Cost a			Laboratory Hours
				Best	Min.	Max.	
107-6-2	**Ethylene Dichloride**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(3)	328,440	193,488	466,836	2,950
		Developmental	(b)(1)(i)(C)	224,060	177,198	273,800	2,547
		Reproductive	(b)(1)(ii)(A) (b)(5)	566,221	426,092	765,601	5,024
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Total		**1,459,725**	**1,072,459**	**1,918,134**	**13,639**
107-21-1	**Ethylene Glycol**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(3)	328,440	193,488	466,836	2,950
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**742,581**	**521,970**	**975,145**	**6,483**
108-10-1	**Methyl Isobutyl Ketone**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Reproductive	(b)(1)(ii)(A) (b)(5)	566,221	426,092	765,601	5,024
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**709,387**	**535,833**	**946,162**	**6,245**
108-31-6	**Maleic Anhydride**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Developmental	(b)(1)(i)(A)	224,060	177,198	273,800	2,547
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Carcinogenicity	(b)(1)(ii)(A)	763,930	611,020	994,590	10,742
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**1,402,130**	**1,116,700**	**1,776,699**	**16,822**
108-90-7	**Chlorobenzene**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(3)	328,440	193,488	466,836	2,950
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**742,581**	**521,970**	**975,145**	**6,483**
108-95-2	**Phenol**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**143,166**	**109,741**	**180,561**	**1,221**

Table B.4: Chemical-Specific Laboratory Costs for Tests Required in Amended HAPs Proposal

CAS Number	Chemical Name	Test Description	Additional Requirements	Cost a			Laboratory Hours
				Best	Min.	Max.	
111-42-2	**Diethanolamine**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(1)(ii)(B) (b)(3)	328,440	193,488	466,836	2,950
		Developmental	(b)(1)(ii)(B)	224,060	177,198	273,800	2,547
		Reproductive	(b)(1)(ii)(B) (b)(5)	566,221	426,092	765,601	5,024
		Neurotoxicity Screen	(b)(1)(ii)(B) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(B)	73,137	52,801	96,412	415
		Total		**1,532,861**	**1,125,260**	**2,014,546**	**14,054**
120-82-1	**1,2,4-Trichlorobenzene**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Developmental		224,060	177,198	273,800	2,547
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**638,200**	**505,680**	**782,109**	**6,080**
126-99-8	**Chloroprene**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Reproductive	(b)(1)(ii)(A) (b)(5)	566,221	426,092	765,601	5,024
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**980,362**	**754,574**	**1,273,910**	**8,557**
463-58-1	**Carbonyl Sulfide**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(3)	328,440	193,488	466,836	2,950
		Developmental		224,060	177,198	273,800	2,547
		Reproductive	(b)(1)(ii)(A) (b)(5)	566,221	426,092	765,601	5,024
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Carcinogenicity	(b)(1)(ii)(A)	763,930	611,020	994,590	10,742
		E. Coli Mutation		5,905	4,420	7,460	48
		Mutation-Somatic Cell Culture		16,066	12,766	19,641	144
		In Vivo Bone Marrow	(b)(1)(ii)(A)	38,302	31,460	45,705	394
		In Vivo Erythrocyte	(b)(1)(ii)(A)	13,915	11,150	16,855	147
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**2,370,979**	**1,796,076**	**3,098,797**	**25,528**
7647-1-0	**Hydrochloric Acid**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Total		**70,029**	**56,940**	**84,149**	**806**

Table B.4: Chemical-Specific Laboratory Costs for Tests Required in Amended HAPs Proposal

CAS Number	Chemical Name	Test Description	Additional Requirements	Cost a			Laboratory Hours
				Best	Min.	Max.	
7664-39-3	**Hydrogen Fluoride**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Subchronic	(b)(3)	328,440	193,488	466,836	2,950
		Developmental		224,060	177,198	273,800	2,547
		Reproductive	(b)(1)(ii)(A) (b)(5)	566,221	426,092	765,601	5,024
		Neurotoxicity Screen	(b)(1)(ii)(A) (b)(1)(iii)(A) (b)(1)(iii)(B)	270,975	218,741	327,748	2,312
		Immunotoxicity	(b)(1)(ii)(A)	73,137	52,801	96,412	415
		Total		**1,532,861**	**1,125,260**	**2,014,546**	**14,054**
7782-50-5	**Chlorine**	Acute Inhalation Toxicity & Modification	(b)(2)	70,029	56,940	84,149	806
		Total		**70,029**	**56,940**	**84,149**	**806**

a) Best, Minimum, and Maximum costs represent the corresponding highlighted Total costs from Table 3. When required, as specified in Table 3, these costs have been scaled, adjusted for inflation, etc. Refer to Table 3 for more detail on cost derivation.

Key to Special Requirements

(b)(1)(i)(A)- mammalian species other than rat
(b)(1)(i)(C)- mammal other than rabbit
(b)(1)(i)(D) - male rat and female mouse
(b)(1)(ii)(A)- via vapor-phase inhalation
(b)(1)(ii)(B)- via inhalation of aerosol
(b)(1)(iii)(A)- 4-hour exposure in acute study
(b)(1)(iii)(B)- 6 hr/day, 5 day/week, 90-day period in subchronic study
(b)(2)- acute test mods, including respiratory sensory irritation assay
(b)(3)- subchronic test mods
(b)(5)- reproductive toxicity and fertility test study mods